

**REMARKS****Interview Summary**

Applicants' Attorney and Applicants' Agent thank the Examiner for granting the telephonic interview of February 12, 2004 and for his willingness to discuss the rejections of record.

The primary subject of the interview was the outstanding rejection of Claim 1 under 35 U.S.C. § 102(b) over U.S. Patent No. 5,711,867 (hereinafter referred to as "the '867 Patent"). In particular, the Examiner's attention was directed to the amendments made to Claim 1 in response to the first Office Action. Claim 1 currently recites that when hematin is derivatized with a polyalkylene glycol group, the polyalkylene glycol group has a molecular weight of about 5,000 to about 15,000. The Examiner stated that hematins derivatized with a polyalkylene glycol of this molecular weight was inherently anticipated by the '867 Patent. However, the Examiner could not provide any evidence that the '867 Patent disclosed any water-soluble hematin derivatized with a polyalkylene glycol of a particular molecular weight. Nevertheless, the Examiner would not acknowledge that the '867 Patent does not disclose a compound having all the limitations of the compounds of Claim 1.

Applicants' attorney also demonstrated that the instant claims are fully supported by the specification and that one skilled in the art would be able to make and use the claimed compounds.

Because no agreement could be reached regarding the novelty of the claims during the interview, the Examiner requested a full written response to the outstanding Office Action.

**Applicants' Invention**

Applicants' invention is directed to a compound comprising hematin derivatized with one or more non-proteinaceous amphipathic groups, where the compound is water-soluble. Claim 1 recites that if the one or more non-proteinaceous amphipathic groups on the hematin are polyalkylene glycol groups, the polyalkylene glycol groups have a molecular weight of about 5,000 to about 15,000.

Advantages of Applicants' Invention

The derivatized hematins of the present invention are water soluble and recyclable, which virtually eliminate the need for toxic reagents and solvents, and thus create an environmentally friendly synthesis for polyaromatic polymers. The water solubility of the derivatized hematin resolves one of the primary limitations of catalysts currently used in the commercial synthesis of polyaromatic polymers, namely by providing a catalyst that is active and stable over a wide range of pHs. In contrast, conventional underivatized hematin is poorly soluble in acidic solutions, such that underivatized hematin has a low catalytic rate in acidic solutions. Moreover, the derivatized hematins of the present invention, in a combination with a template, reduce the amount of branching during polymerization of polyaromatic polymers, leading to a structurally more consistent product.

Rejection of Claim 1 Under 35 U.S.C. §§ 102(b) or 103(a)

Claim 1 is rejected under 35 U.S.C. § 102(b) as being anticipated by or under 35 U.S.C. § 103(a) as being obvious over Chem. Abstract 128: 162418 (the abstract for the '867 Patent).

The Examiner states that limitations from the specification or remarks as to how the compound is produced are not read into the claim. Applicants do not understand the Examiner's remarks. The method of preparation is not relied upon for the patentability of Claim 1. Instead, patentability is based upon the fact that the '867 Patent does not disclose a water-soluble hematin derivatized with one or more polyalkylene groups having a molecular weight of about 5,000 to about 15,000. The '867 Patent does not disclose the molecular weight of the hematin derivatized with polyethylene glycol; there is no value of x specified for the compound shown in the third line of Column 11 and 12. Thus, the '867 Patent does not disclose a derivatized hematin that has all of the limitations of Claim 1.

The Examiner further states that the claim as presented is included in the broad teachings of the '867 Patent because it reads on a compound comprising hematin derivatized with polyalkylene glycols. This statement fails to recognize that when the compound of Claim 1 comprises hematin derivatized with one or more polyalkylene glycols, the polyalkylene glycols have a molecular weight of about 5,000 to about 15,000. In order for a reference to anticipate a claim, it must teach all of the limitations of the claim. It is insufficient for claimed subject matter to simply fall within the broad teachings of a reference.

The Examiner also states that no factual evidence has been presented to show why the products of the reference would not have the claimed properties. In particular, the Examiner asserts that the claimed characteristic of molecular weight is considered to be inherent in the prior art. It is respectfully requested that the Examiner provide evidence that the polyalkylene glycols disclosed in the '867 Patent have a molecular weight of about 5,000 to about 15,000. Applicants are unable to find any disclosure of a water-soluble hematin derivatized with one or more polyalkylene glycols of a specific molecular weight. Applicants further note that molecular weight is a physical description of a polyalkylene glycol that indicates its size, and is not a functional property of the molecule. The '867 Patent must specifically indicate the molecular weight of a polyalkylene glycol that a water-soluble is derivatized with in order to anticipate Claim 1.

Claim 1 is also not obvious over the '867 Patent. The '867 Patent is directed to an electrochemical separation apparatus that utilizes metalloporphyrins and metallophthalocyanines. In the separation apparatus, the metalloporphyrins and metallophthalocyanines are covalently bound to a solid support, such that they are not water soluble. One synthetic route, shown in Columns 11 and 12, involves a hematin that is derivatized with polyethylene glycol of an unspecified molecular weight. This hematin, referred to in the '867 Patent as "PEGolated hematin," is simply an intermediate in the preparation of a separation apparatus. The PEGolated hematin is not isolated, so that the functional properties of the PEGolated hematin are not recognized.

According to *In re Lalu*, an obviousness rejection cannot be made if the properties of a compound are not recognized:

In obviousness rejections based on close similarity in chemical structure, the necessary motivation to make a claimed compound, and thus the *prima facie* case of obviousness, rises from the expectation that compounds similar in structure will have similar properties. \* \* \* No common-properties presumption rises from the mere occurrence of a claimed compound at an intermediate point in a conventional reaction yielding a specifically named prior art compound. . . . Absent that presumption or other evidence of motivation, it cannot be said that it would have been obvious to stop the process for synthesizing the disclosed end product and isolate the claimed intermediate. 223 USPQ 1257, 1259 (Fed. Cir. 1984).

Congruent with this standard, the *Lalu* court held that a compound represented by the structural formula  $C_nF_{2n+1}(CH_2)_bSO_2Z$  was not obvious over a compound represented by the structural formula  $C_nF_{2n+1}CH_2SO_2Z$ , where the latter compound was simply an intermediate in a synthesis. The sole structural distinction between the compounds was in the length of the methylene linker between the perfluorocarbonyl and the sulfonyl moieties. In the first compound,  $b$  is an integer from 2 to 20, such that there are from 2 to 20 methylene groups in the linker. In the second compound, the linker is a single methylene group. Thus, a claimed compound differing by as little as a single methylene group from a previously disclosed compound was not obvious, because the previously disclosed compound was only present as an intermediate. The properties of the prior art compound were never disclosed.

The present scenario closely parallels the scenario presented in *Lalu*. First, in *Lalu* the functional properties of the compounds disclosed in the prior art reference were never appreciated because the relevant compound was only an intermediate in a synthetic pathway. Similarly, the '867 Patent prepares water-soluble hematin derivatized with a polyalkylene glycol group only as an intermediate, and the properties of the derivatized hematin are never recognized. Notably, the '867 Patent does not even recognize that the derivatized hematin compound shown in line 3 of Columns 11 and 12 is water soluble (water solubility is an important element of the present invention, as it allows for a high catalytic rate under environmentally-friendly conditions). The hematin compound is only disclosed to be soluble in dioxane and acidified ethanol. Second, the size of the alkylene glycol groups in the present compounds, when present, is different than the size of the alkylene glycol group in the compounds of the '867 Patent, which is unspecified. This is analogous to *Lalu* in that the non-obvious claimed compound was differentiated from the prior art compound only by the number of methylene groups in a linker. According to the standard set forth in *Lalu*, a compound is not obvious if a prior art compound was simply an intermediate compound with unrecognized properties, even if the compounds are structurally similar. Thus, the compounds of Claim 1 are not obvious in view of the '867 Patent.

Because the '867 Patent does not teach all of the limitations of Claim 1, Claim 1 is novel over the '867 Patent. Similarly, the '867 Patent does not teach all of the limitations of Claims 2-4. In addition, it has been demonstrated that Claim 1 (and, by extension, Claims 2-4) are not obvious over the '867 Patent. Reconsideration and withdrawal of the rejection are respectfully requested.

Rejection of Claim 45 Under 35 U.S.C. § 103(a)

The Examiner states that Claim 5 is rejected under 35 U.S.C. § 103(a) as being obvious over the '867 Patent. Claim 5 was previously canceled, and Applicants make the assumption that the rejection is with respect to Claim 45.

The Examiner states that the '867 Patent discloses the use of a diaminohexane as a derivatizing group for hematin. The Examiner further states that it would have been obvious to select diaminohexane or another group to replace other amphipathic groups.

Although the '867 Patent does disclose a hematin that is derivatized with diaminohexane, this hematin is *water-insoluble*. The diaminohexane-derivatized hematin is attached to a solid substrate, which renders it water-insoluble. Unlike the polyethylene glycol-derivatized hematin, the diaminohexane-derivatized hematin is never present as a water-soluble intermediate.

As discussed above, obviousness is based upon the expectation that compounds similar in structure will have similar properties. The diaminohexane-derivatized hematin disclosed in the '867 Patent is water-insoluble, so that one of ordinary skill in the art would have had no expectation that hematin derivatized with an amine-containing group would be water soluble. Moreover, the '867 Patent does not teach or otherwise suggest how to select derivatizing groups, because the '867 Patent has no disclosure relating to whether particular hematin derivatives are water-soluble. The '867 Patent selects derivatizing groups for hematin based simply upon their ability to attach to both hematin and a solid support (i.e., to serve as "spacer arms"). Any potentially water-soluble hematin-spacer arms derivatives *were taught only as intermediates* in preparing hematin that was covalent linked (through the spacer arm) to a solid support, so that the properties of the hematin-spacer arm derivative were never appreciated. Thus, the '867 Patent provides no guidance in how to select a derivatizing group with which to prepare a water-soluble hematin.

Because the diaminohexane-derivatized aminoxyhexane disclosed in the '867 Patent is water-insoluble and because obviousness is based upon the expectation that structurally similar compounds will have similar properties, the diaminohexane-derivatized hematin of the '867 cannot render the instantly-claimed water-soluble hematin obvious. Thus, Claim 45 is not obvious over the '867 Patent. Reconsideration and withdrawal of the rejection are respectfully requested.

CONCLUSION

There is no disclosure or suggestion of Applicants' invention, as claimed, in U.S. Patent No. 5,711,867. Therefore, Applicants' invention meets the requirements of 35 U.S.C. §§ 102 and 103.

In view of the above amendments and remarks, it is believed that all claims are in condition for allowance, and it is respectfully requested that the application be passed to issue. If the Examiner feels that a telephone conference would expedite prosecution of this case, the Examiner is invited to call the undersigned.

Respectfully submitted,

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